



07-28-06

IPW

CASE ON/4-32665A

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV72727432545

Express Mail Label Number

July 27, 2006

Date of Deposit

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF  
BAULCH-BROWN ET AL.

INTERNATIONAL APPLICATION NO: PCT/EP03/09972

FILED: 8 SEPTEMBER 2003

U.S. APPLICATION NO: 10/526,282 ✓

35 USC §371 DATE: 16 FEBRUARY 2006

FOR: COMBINATION THERAPY COMPRISING A BISPHOSPHONATES  
AND A HMG-COA REDUCTASE INHIBITOR

**MS: Amendment**

Commissioner for Patents

PO Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants believe this paper is being filed before the mailing date of a first Office action on the merits, and so under 37 C.F.R. §1.97(b)(3) no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-0134.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

The asterisked references were cited in the International Search Report and copies of said references were forwarded by the International Bureau; therefore, copies are not enclosed.

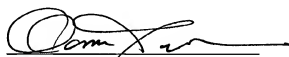
ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.S./

A copy of a British Search Report is enclosed citing two references. WO 99/45923 is already cited in the International Search Report, and the non-asterisked U.S. Patent cited is not provided pursuant to the waiver of requirement under 37 CFR 1.98(a)(2)(i) issued in the Official Gazette dated August 5, 2003.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

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## INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

ATTY. DOCKET NO.  
ON4-32665A  
APPLICATION NO.  
10/526,282  
APPLICANT  
BAULCH-BROWN ET AL.  
FILING DATE  
FEBRUARY 16, 2006

Group

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA 2001/025028*	9/27/01	Fisher et al.			
	AB 2002/028826*	3/7/02	Chen et al.			
	AC 2002/061901*	5/23/02	Chen et al.			
	AD 6,080,779	6/27/00	Gasper et al.			
	AE					
	AF					
	AG					
	AH					
	AI					
	AJ					
	AK					
	AL					

## FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	AM 99 45923*	9/16/99	WO			<input type="checkbox"/>	<input type="checkbox"/>
	AN 99 58505*	11/18/99	WO			<input type="checkbox"/>	<input type="checkbox"/>
	AO 02 28270*	4/11/02	WO			<input type="checkbox"/>	<input type="checkbox"/>
	AP					<input type="checkbox"/>	<input type="checkbox"/>
	AQ					<input type="checkbox"/>	<input type="checkbox"/>

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

AR	Berkhout et al., "The novel cholesterol-lowering drug SR-12813 inhibits cholesterol synthesis via an increased degradation of 3-hydroxy-3-methylglutaryl-coenzyme A reductase," Journal of Biological Chemistry, American Society of Biological Chemists, Vol. 271(24), pp. 14376-14382 (1996)*		
AS	Garrett et al., "Statins and bone formation," Current Pharmaceutical Design, Vol. 7(8), pp. 715-736 (2001)*		
AT	Gebhardt et al., "Effects of Pravastatin, a hydroxymethylglutaryl-CDA reductase inhibitor, on two human tumour cell lines," Journal of Cancer Research and Clinical Oncology, Vol. 121(6), pp. 343-349 (1995)*		
EXAMINER	/Marcos Sznaidman/	DATE CONSIDERED	11/24/2008

\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.S./

**INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)

Group

EXAMINER  
INITIAL

**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent pages, Etc.)

DA	Lee et al., "Inhibition of the 3-hydroxy-3-methylglutaryl-coenzyme A reductase pathway induces p53-independent transcriptional regulation of p21(WAF1/CIP1) in human prostate carcinoma cells," <i>The Journal of Biological Chemistry</i> , Vol. 273(17), pp. 10618-10623 (1998)*
DB	Larsson, "HMG-CoA reductase inhibitors: Role in normal and malignant cells," <i>Critical Reviews in Oncology/Hematology</i> , Vol. 3(22), pp. 197-212 (1996)*
DC	Santini et al., "Pamidronate (P) induces modifications of circulating angiogenetic factors in cancer patients," <i>European Journal of Cancer</i> , Vol. 37, pp. S262-S263 (2001)*
DD	Witters et al., "Inhibition of growth of human breast cancer cell lines with the combination of zoledronic acid and a COX-2 inhibitor," <i>European Journal of Cancer</i> , Vol. 37, pp. S78 (2001)*
DE	Pecherstorfer et al., "A randomized study of ibandronate and pamidronate in hypercalcemia of malignancy (HCM). Ibandronate is more effective in the subset of patients with severe HCM and has at least equal efficacy to pamidronate in HCM patients with less elevated baseline calcium levels," <i>European Journal of Cancer</i> , Vol. 37, pp. S171 (2001)*
DF	Oura et al., "Effective alendronate therapy against a bone metastasis occurring during docetaxel therapy for breast cancer—a case report," <i>Cancerlit</i> . XP002232827 Abstract*
DG	Freyer et al., "Palliative hormone therapy, low dose chemotherapy and bisphosphonate in breast cancer patients with bone marrow involvement and pancytopenia; report of pilot experience," <i>European Journal of Internal Medicine</i> , Vol. 11, pp. 329-333, (2000)*
DH	Shipman et al., "Bisphosphonates induce apoptosis in human myeloma cell lines: a novel anti-tumor activity," <i>British Journal of Haematology</i> , Vol. 98(3), pp. 665-672 (1997)*
DI	
DJ	
DK	
DL	
DM	
DN	

EXAMINER

/Marcos Sznajdman/

DATE CONSIDERED

11/24/2008

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